

**K880278 MALLEABLE PTFE COATED BRAIN SPATULAE**Feb 11, 1988  
20 days to decisionK880278 · Product code: **HAO** · Neurology  
Source: <https://www.510kdatabase.net/k880278/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Instrument, Surgical, Non-powered (HAO)
Date received	Jan 22, 1988
Decision date	Feb 11, 1988
Days to decision	20 days
Third-party review	No

**APPLICANT**

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Company	<b>Downs Surgical , Ltd.</b>
Location	Mchenry, IL, US
Contact	GEOFFREY W DOWN
510(k) history	60 submissions · 60 cleared · 1980-1990

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k880278/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 22, 2026